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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,146	06/26/2002	Teresa Compton	960296.98342	6687

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/942,146	COMPTON ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6 and 8-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6 and 8-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: sequence letter

DETAILED ACTION

Response to Amendment

This is a response to the amendment, paper No. 15, filed 03/12/04. Claims 6 and 8-11 have been amended. Claim 7 has been canceled. Claims 6 and 8-12 are pending and considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 6-10 are still rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. In response to Office Action, Applicants amend claim 6 as a glycoprotein O polypeptide and submit that 112 2nd paragraph rejection should be withdrawn in view of the amendment.

4. Applicants' amendment has been carefully viewed and considered. However, it is not persuasive for overcoming the rejection in that the metes and bounds of glycoprotein O polypeptide are not defined as CMV glycoprotein O. It read on any or all glycoprotein O polypeptide. The claims are interpreted in light of the specification; however, the specification does not give the definition of "glycoprotein O polypeptide". Therefore, the rejection is still maintained. This affects the dependent claims 8-10.

5. In addition, the recitation of a fragment in claim 10 is still rejected since the recitation of a fragment is still not defined.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 6 and 8-12 are still rejected under 35 U.S.C. 112, first paragraph on the same ground as stated in the previous Office Action, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention (Examiner presumes that claims 8-10 are dependent on the independent claim 6).

8. In response to the Office Action, Applicants traverse the rejection by amending claim 6 and submitting that in specification of page 4, applicants has demonstrated and observed a does-dependent inhibition of CMV infection by anti-gO serum. Therefore, one of skill in the art would apply the Applicants' observation in vitro into a clinical application and obtain Applicants' predicted results in CMV patients.

9. Applicants' amendment as well as argument has been respectfully considered; however, it is not found persuasive because claim 6 was amended to be broader that read on any or all "glycoprotein O" polypeptide or any truncated that are not even not limit to CMV. Applicants do not teach any or all "glycoprotein O" polypeptide or its truncated form is able to induce a neutralizing activity against CMV infection in vitro and in vivo. It has many experiments need to be done before any "glycoprotein O" polypeptide or its truncated form is concluded as an anti-CMV drug.

10. In view of the unpredictable field of CMV treatment and prevention as described in the previous Office Action, considering the broad scope of rejected claims and large quantity of experimentation needed, it is still concluded that undue experimentation would be required to enable the intended claim. The rejection is maintained.

New Grounds of Rejections:

Sequence requirements

This application contains sequence disclosure in **Fig. 3** that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Full compliance with the sequence rules by **inserting a proper SEQ ID NO in Fig. 3** is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

Specification

11. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter in claim 8, " transmembrane anchor region." See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Please explain and describe which region is the " transmembrane anchor region" as cited in claim 8.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14. Claim 8 recites the limitation "the" in transmembrance anchor region. There is insufficient antecedent basis for this limitation in the claim. Moreover, the metes and bounds of " transmembrane anchor region" and " a portion of transmembrane anchor region" are not defined. The claim is interpreted in light of the specification; however, the specification does not

teach what the definition of the recited " transmembrane anchor region" is. Therefore, the claim is considered indefinite.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 6, 11 and 12 rejected under 35 U.S.C. 102(b) as being anticipated by Gonczol et al. (J. Virol. 1986, Vol. 58, No. 2, pp. 661-664).

17. Gonczol et al. teach the several compositions that are used for immunizing the animal guinea pigs to induce neutralizing antibodies. Each of composition comprises the isolated HCMV antigen related envelope protein (gA) or other CMV envelope glycoprotein respectively (Table 1 on page 661). They further teach that the monoclonal antibodies are able to recognize the 130K and 58K glycoproteins (see page 663 the second paragraph on the left col.), indicating the Ag protein isolated form the CMV is a glycoprotein. While the reference does not explicitly mention the pharmaceutical carrier, it is well known in the art that any composition that used for immunization is inherently contained in a solution, which is a pharmaceutical accepted carrier. Therefore, the claimed invention is anticipated by the cited reference.

18. Applicants are reminded that because the rejected claims do not point out what the structure of claimed glycoprotein is, the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products.

19. Claims 6, 11 and 12 rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (J. Virol. 1986, Vol. 58, No. 2, pp. 661-664).

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (J. Virol. 1997, Vol. 71, No. 4, pp. 3090-3097).

22. Claimed invention is drawn to a composition or anti-CMV drug comprising a full-length viral glycoprotein O, which can effectively neutralize the CMV infection. The composition also comprises a pharmacologically acceptable carrier.

23. Li et al. teach that the human CMV gCIII complex comprises a third protein with molecular weight 125 kD (gp125) that is different from other glycoprotein H and L (See entire document, especially page 3092, 3093, 3094 and 3097). While Li et al. do not teach that the glycoprotein gp125 is a glycoprotein O of CMV and it is capable of inducing a neutralizing antibody, the physical characteristics of the protein, such as it is isolated from the same CMV gCIII complex with same molecular weight as it is disclosed in the current application, indicating that the protein is the same glycoprotein O of CMV. Li et al. do not teach that the protein is contained in a pharmacologically accepted carrier.

24. Therefore, it would have been obvious for a person with ordinary skill in the art to be motivated to constitute the isolated glycoprotein from the CMV gCIII complex with other pharmacologically accepted carrier, such as PBS, and use the composition to immunize an animal to induce an neutralizing antibody against CMV absence unaccepted result. As there are no unexpected results have been provided, hence the claimed invention as a whole is prima facie obvious absence unexpected results.

25. Claims 6 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huber et al. (J. Virol. 1997, Vol. 71, No. 7, pp. 5391-5398) and Gretch et al. (J. Virol. 1988, Vol. 62, No. 3, pp. 875-881).

26. Claimed invention is drawn to a composition or anti-CMV drug comprising a full-length viral glycoprotein O, which can effectively neutralize the CMV infection. The composition also comprises a pharmaceutical acceptable carrier.

27. Huber et al. teach that the composition of human CMV gCIII complex comprises a third protein with molecular weight 145 kD that is different from other glycoprotein H and L (See page 5391 and 5396-5398). Huber et al do not teach that the gp145 of CMV gCIII is capable of neutralizing CMV infection.

28. Gretch et al. teach the human CMV gCIII complex comprises three glycoproteins molecular weight 240 kD, 145 kD (gp145) and 85 Kd (gp85) respectively and the monoclonal antibodies that recognize the glycoprotein from CMV gCIII complex are capable of neutralizing the infectivity of HCMV (pages 875, 877-879 and the last paragraph on page 880).

29. Therefore, it would have been obvious for a person with ordinary skill in the art to be motivated to constitute the isolated glycoprotein from the CMV gCIII complex with other pharmaceutical accepted carrier, such as PBS, and use the composition to immunize an animal to induce an neutralizing antibody against CMV absence unaccepted result because Gretch already point out that the antibody against the CMV gCIII complex is a neutralizing antibody (last paragraph on page 880). As there are no unexpected results have been provided, hence the claimed invention as a whole is prima facie obvious absence unexpected results.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li
Art Unit 1648
May 12, 2004

JAMES HOUSEL 5/17/04
SUPERVISORY PATENT EXAMINER
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